EXHIBIT G

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September 18, 2019

VIA MOD E-FILE

Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building, Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Re: ALJ Appeal No.: 1-8630709341
Decision Date: September 12, 2019
Appellant/Beneficiary: D. Christenson
HICN: 7QR9QM0QP33
Service: E0766
Dates of Service: 11/3/2018; 12/3/2018; 1/3/2019
Our Ref.: 19-296

Dear Medicare Appeals Council:

David Christenson appeals the attached September 12, 2019 unfavorable decision by Administrative Law Judge Scott Watson with respect to the above-identified case. See Attachment 2. Appellant appeals the unfavorable portion of the decision based on mistake of fact and mistake of law.

I. The issues to be considered in the appeal are:

1. Did the ALJ make a mistake of law when he determined that LCDs are binding on ALJs?

2. Did the ALJ make a mistake of law when he failed to recognize and/or apply the principle of collateral estoppel?

3. Did the ALJ make a mistake of law when he applied an LCD that had been invalidated by operation of Medicare regulations?

4. Should the Appellant's request for coverage be granted?

II. Introduction

Mr. Christenson was prescribed an Optune system for his recurrent glioblastoma multiforme (GBM) (a kind of brain tumor) in early 2016. The Optune system delivers tumor treatment field therapy (TTFT). TTFT creates an electrical field that disrupts and corrupts the division of cancer cells and leads to the death of such cells. In 2011 and 2015, the FDA approved, through its more rigorous review process, the Optune device to deliver TTFT, finding it to be safe and effective for the treatment of glioblastomas. The initial FDA approval was for recurrent glioblastoma. The FDA then approved the Optune device for newly diagnosed glioblastomas. During the most recent clinical trial for glioblastomas (which included newly diagnosed and recurrent GBM), the interim TTFT results were so compelling (i.e., the treatment was able to show significant clinical benefit) that the Data Safety Monitoring Board recommended early termination of the study to enable patients not receiving the treatment to cross over and receive the treatment deeming it to be unethical to withhold TTFT from those not receiving it. The FDA agreed.

All the claims at issue were denied by the Medicare contractor citing LCD L34823 which simply states TTFT will be denied as not reasonable and necessary. The QIC denied the claims citing the LCD. Significantly, Medicare coverage for this beneficiary has been established. Two different Medicare ALJs determined that TTFT met Medicare coverage criteria for this beneficiary.

On July 18, 2019, the DMACs revised LCD L34823. When an LCD is revised after an LCD challenge is filed, that has the same effect as a judicial ruling that the LCD was invalid. See 42 C.F.R. §426.420(b). Nonetheless, the ALJ applied the old version of LCD L34823 and denied the claims asserting, "I am bound to follow Medicare rules and regulations." Decision at 4. No citation to any statute of regulation indicating that LCDs are binding on ALJ was provided. Further, the ALJ did not address any of the other issues raised, discuss the effect of the July 18, 2019 LCD revision, or the prior ALJ rulings. Although the ALJ conceded TTFT had been effective staving off for Mr. Christenson's otherwise fatal illness for over 3.5 year and had extended his life by seven-fold, the Judge Watson found no reason to deviate from the invalidated LCD. The decision reflects numerous errors of law and fact.

III. Errors of Law and Fact

Turning to the ALJ's decision, the ALJ denied coverage on the basis of LCD L34823. That was in error.

A. Collateral Estoppel

Medicare coverage of TTFT for Mr. Christenson repeatedly and explicitly has been found. See ALJ Nos. 1-8285652321 and 1-8416229632. These two prior favorable ALJ decisions are for other dates of service for the same device for the same condition which were

denied on the same basis. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues. As noted by a unanimous Supreme Court:

> We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality. When an administrative agency is acting in a judicial capacity and resolves dispute issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply res judicata to enforce repose. Such repose is justified on the sound and obvious principle of judicial policy that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise. To hold otherwise would, as a general matter, impose unjustifiably upon those who have already shouldered their burdens, and drain the resources of an adjudicatory system with disputes resisting resolution. The principle holds true when a court has resolved an issue, and should do so equally when the issue has been decided by an administrative agency, be it state or federal, which acts in a judicial capacity.

See Astoria Federal Savings and Loan Assoc. v. Solimino, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). No basis exists for the Secretary to ignore the prior coverage rulings for this Medicare beneficiary. The ALJ did not even discuss the issue in his decision. Accordingly, coverage of Mr. Christenson's TTFT device should be ordered.

B. Failure to Comply With 42 C.F.R. § 405.1062(a)/(d)

As noted above, ALJs are not bound by LCDs and only give deference to them. See 42 C.F.R. § 405.1062(a). Further, ALJs are commanded to conduct a *de novo* review of the case. See 42 C.F.R. § 405.1062(d). Accordingly, there must be some fact(s) that a beneficiary could present that would cause the ALJ to not defer to an LCD. To hold otherwise would contradict the command of § 405.1062(a).

In the present case, Mr. Christenson presented evidence that, *after LCD L34823 issued*:

1) the FDA approved the device as safe and effective for newly diagnosed GBM;
2) Published studies demonstrated the conclusive safety and effectiveness of TTFT;
3) The consensus of experts is that TTFT is safe and effective;
4) NCCN guidelines gave TTFT a higher level recommendation;
5) The most recent clinical trial of TTFT for GBM was halted because it would have been unethical to deny TTFT to the study participants that were not selected for treatment;
6) TTFT became widely adopted by the provider and payor communities; and
7) TTFT became the standard of care for newly diagnosed GBM.

Of course, Mr. Christenson also presented evidence of his own medical condition. Mr. Christenson had a life expectancy of six months, but has exceeded that by more than three years and has not shown any signs of progression.

In his decision, the ALJ ignored the foregoing and simply stated he was bound by the LCD. Respectfully, the ALJ's reasoning in this regard reflects an error in both the evidence on which an ALJ's decision is to be based, and the ALJ's role in the process. As prescribed by 42 C.F.R. § 405.1000(d), an ALJ's decision is based on the "administrative record", i.e., the record in the specific case. Thus, the fact that the LCD has not yet been revised should be considered in view of the Medicare beneficiary's condition and the overwhelming evidence that TTFT met Medicare's coverage criteria before the dates of service.

In the present case, Mr. Christenson offered evidence that TTFT had conferred a specific benefit to him, and is, literally, a life-saving treatment for his deadly form of brain cancer. The ALJ conceded the medical benefit to Mr. Christenson. It is difficult to imagine more compelling facts that support Medicare coverage. The ALJ's refusal to consider that evidence was an error of law.

C. ALJ's Are Not Bound By LCDs

Under the rules applicable to Medicare, ALJs and the MAC are not bound by an LCD but must explain their decision if they decline to follow one. 42 C.F.R. § 405.1062. Thus, even in the face of a perfectly valid LCD excluding coverage, an ALJ or the MAC may decline to follow it and order coverage. In this case, of course, the LCD has become invalid through the revision that issued on July 18, 2019. In the present case, the ALJ's claim that he is bound to follow an LCD contradicts the regulation. This is an error of law.

D. The Invalid LCD L34823 Does Not Apply

On July 18, 2019, the DMACs revised LCD L34823. The revision of an LCD after an LCD challenge has been filed has the same effect as a judicial ruling the LCD was invalid. Accordingly, the ALJ's application of the invalid LCD was an error of law.

E. Coverage Should Be Ordered

Where there is no applicable statute, NCD, or LCD, whether durable medical equipment should be covered is guided by 42 C.F.R. § 414.202. Further, to be covered, the device must be medically reasonable and necessary for the particular beneficiary.

In the present case, there was no dispute that the Optune device qualifies as DME. The evidence in the record showed the following: 1) the device can withstand repeated use (indeed, that is how the treatment works); 2) not being consumable in nature and having no moving parts, the device has an expected life of at least three years; 3) the device is primarily and customarily used to serve a medical purpose (indeed, it has no other purpose); 4) the device is generally not useful in absence of illness or injury (indeed, no other use is known); and 5) the device is

appropriate for use in the home (indeed, it is wearable and can be used both indoors and outdoors). No evidence to the contrary was submitted. Accordingly, the Optune device qualifies as DME.

With regard to whether the device is medically reasonable and necessary for Mr. Christenson, the data from the clinical trial for newly diagnosed glioblastomas demonstrated such remarkable effectiveness that the study was terminated early to enable those not receiving treatment during the clinical trial to receive the treatment. The FDA approved the device as effective. TTFT is included in the NCCN guidelines. Thus, the experts agree that the peer-reviewed literature supports offering to those afflicted with a GBM.

TTFT satisfies the other coverage criteria – the consensus of experts and widespread adoption. The consensus of experts (reflected in the NCCN guidelines and adoption by all the major medical centers in the United States), and acceptance by the relevant medical community (again in view of the inclusion in practice guidelines, the device has been prescribed in every state by hundreds of clinicians and is covered by all major payers), strongly support Medicare coverage. Further, of course, all of this evidence demonstrates that the medical community considers TTFT safe and effective.

Off course, Mr. Christenson's treating physician prescribed the device to treat his GBM. Where, as here, the treating physician makes a determination, significant reliance should be placed on that determination or there must be a reasoned basis for failing to do so. *See Klementowski v. Secretary of HHS*, 801 F. Supp. 1022 (W.D.N.Y. 1992) citing *State of New York v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991).[1] This is especially compelling where, as in the case herein, there is "no direct conflicting evidence." *Kuebler v. Secretary of U.S. Dept. of Health & Human Services*, 579 F. Supp. 1436 (D.C. N.Y. 1984). In fact, the Ninth Circuit has commented that the treating physician's opinion should not be rejected without clear and convincing evidence to do so. *Vista Hill Foundation, Inc. v. Heckler*, 767 F.2d 556 (9th Cir. 1985). There is no "reasoned basis" for refusing to accept the opinion of Mr. Christenson's treating physician. *See Heart 4 Heart, Inc. v. Sebelius*, 2014 WL 3028684 (C.D. Illinois July 3, 2014) at 8 - 9.

Accordingly, coverage of Mr. Christenson's TTFT device should be ordered.

IV. Conclusion

The Optune system was reasonable and medically necessary when it was provided to Mr. Christenson. The denial is contrary to the facts and law. The ALJ committed fundamental errors of law and fact when he denied a Medicare beneficiary coverage of a service which has extended his life. Based on the foregoing, the Council should reverse Judge Watson's decision and order coverage of the Optune system for Mr. Christenson consistent with the standard of care.

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[1] See also *Roddy v. Astrue*, 705 F.3d 631,636, 637 (7th Cir. 2013); *Senn v. Astrue*, 2013 WL 63257 (E.D. Wis.).

Please contact me if you have any questions regarding this appeal.

Yours very truly,

Debra Pistorino Parrish

Enclosures:
Attachment 1: Appointment of Representative
Attachment 2: September 12, 2019 ALJ Decision

cc: D. Christenson
Maximus
C2C Innovative Solutions, Inc.
Novocure, Inc.

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January 3, 2020

VIA E-file
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, DC 20201

RE: Request for Escalation
Appellant/Medicare Beneficiary: David Christenson
HICN: 7QR9QM0QP33
ALJ Decision Date: Sept. 12, 2019
ALJ Appeal No.: 1-8630709341
Council No.: M-19-2777 (filed Sept. 18, 2019)
Our Ref: 19-296

Dear Medicare Appeals Council:

Mr. David Christenson has received three favorable ALJ decisions finding TTFT meets Medicare coverage criteria for him. See ALJ Nos. 1-8285652321, 1-8416229632 and 1-8416270832. The Secretary chose not to appeal the decisions and each of them has become final. The Secretary is barred by the doctrine of collateral estoppel/issue preclusion from re-litigating those issues with respect to Mr. Christenson. As noted by a unanimous Supreme Court, "We have long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have attained finality." *See Astoria Federal Savings and Loan Assoc. v. Solimino*, 501 U.S. 104, 107-8 (1991) (internal citations and quotations omitted). The application of issue preclusion would not work as basic unfairness against the Secretary and there are no special circumstances that would make it unfair to apply the doctrine.

The above-captioned Medicare beneficiary appeal has been pending for more than 90 days. Accordingly, pursuant to 42 C.F.R. §405.1132, Mr. Christenson requests escalation of the above-captioned claims to District Court.

Sincerely,

Debra M. Parrish for
Medicare Beneficiary David Christenson